

# HOUSE BILL 1141

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CF SB 750

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By: **Delegates Pendergrass, Hammen, Frank, Hubbard, A. Kelly, and  
Pena-Melnyk**

Introduced and read first time: February 10, 2012

Assigned to: Health and Government Operations

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## A BILL ENTITLED

1 AN ACT concerning

2 **Maryland Health Care Commission – Cardiac Surgery and Percutaneous**  
3 **Coronary Intervention Services**

4 FOR the purpose of requiring, with a certain exception, a certificate of need for the  
5 establishment of percutaneous coronary intervention (PCI) services; requiring,  
6 beginning on a certain date, an acute general hospital to have a certificate of  
7 conformance before the hospital may establish primary PCI services or  
8 nonprimary PCI services; prohibiting the Maryland Health Care Commission  
9 from issuing a certificate of conformance unless the Commission finds that the  
10 proposed primary PCI services or proposed nonprimary PCI services meet  
11 certain standards; providing that a certificate of conformance is not required,  
12 notwithstanding certain provisions of this Act, for an acute general hospital to  
13 establish primary PCI services under certain circumstances; requiring an acute  
14 care hospital that provides cardiac surgery or PCI services under certain  
15 authorization to obtain and maintain a certificate of ongoing performance to  
16 continue to provide cardiac surgery services, primary PCI services, or  
17 nonprimary PCI services; requiring an acute general hospital that is providing  
18 nonprimary PCI services under a research waiver issued by the Commission to  
19 obtain a certificate of conformance for its nonprimary PCI services before it may  
20 obtain a certificate of ongoing performance to provide the nonprimary PCI  
21 services; requiring the Commission to adopt certain regulations; requiring the  
22 regulations to include certain items; establishing certain parameters for the  
23 process established by the Commission for issuing a certificate of conformance;  
24 authorizing a certain hospital, notwithstanding certain provisions of this Act, to  
25 provide nonprimary PCI services until the Commission takes certain actions;  
26 defining certain terms; and generally relating to the regulation of cardiac  
27 surgery and percutaneous coronary intervention services by the Maryland  
28 Health Care Commission.

29 BY repealing and reenacting, without amendments,

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 Article – Health – General  
2 Section 19–120(j)(1)  
3 Annotated Code of Maryland  
4 (2009 Replacement Volume and 2011 Supplement)

5 BY repealing and reenacting, with amendments,  
6 Article – Health – General  
7 Section 19–120(j)(2)  
8 Annotated Code of Maryland  
9 (2009 Replacement Volume and 2011 Supplement)

10 BY adding to  
11 Article – Health – General  
12 Section 19–120.1  
13 Annotated Code of Maryland  
14 (2009 Replacement Volume and 2011 Supplement)

15 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF  
16 MARYLAND, That the Laws of Maryland read as follows:

17 **Article – Health – General**

18 19–120.

19 (j) (1) A certificate of need is required before the type or scope of any  
20 health care service is changed if the health care service is offered:

21 (i) By a health care facility;

22 (ii) In space that is leased from a health care facility; or

23 (iii) In space that is on land leased from a health care facility.

24 (2) This subsection does not apply if:

25 (i) The Commission adopts limits for changes in health care  
26 services and the proposed change would not exceed those limits;

27 (ii) The proposed change and the annual operating revenue that  
28 would result from the addition is entirely associated with the use of medical  
29 equipment;

30 (iii) The proposed change would establish, increase, or decrease  
31 a health care service and the change would not result in the:

32 1. Establishment of a new medical service or elimination  
33 of an existing medical service;

1                                   2.     Establishment of [an open heart] A CARDIAC surgery,  
2 organ transplant surgery, or burn or neonatal intensive health care service;

3                                   **3.     EXCEPT AS PROVIDED IN § 19–120.1 OF THIS**  
4 **SUBTITLE, ESTABLISHMENT OF PERCUTANEOUS CORONARY INTERVENTION**  
5 **SERVICES;**

6                                   [3.] 4.     Establishment of a home health program,  
7 hospice program, or freestanding ambulatory surgical center or facility; or

8                                   [4.] 5.     Expansion of a comprehensive care, extended  
9 care, intermediate care, residential treatment, psychiatry, or rehabilitation medical  
10 service, except for an expansion related to an increase in total bed capacity in  
11 accordance with subsection (h)(2)(i) of this section; or

12                                   (iv) 1.     At least 45 days before increasing or decreasing the  
13 volume of one or more health care services, written notice of intent to change the  
14 volume of health care services is filed with the Commission;

15                                   2.     The Commission in its sole discretion finds that the  
16 proposed change:

17                                   A.     Is pursuant to the consolidation or merger of two or  
18 more health care facilities, the conversion of a health care facility or part of a facility  
19 to a nonhealth–related use, or the conversion of a hospital to a limited service hospital;

20                                   B.     Is not inconsistent with the State health plan or the  
21 institution–specific plan developed and adopted by the Commission;

22                                   C.     Will result in the delivery of more efficient and  
23 effective health care services; and

24                                   D.     Is in the public interest; and

25                                   3.     Within 45 days of receiving notice under item 1 of this  
26 item, the Commission notifies the health care facility of its finding.

27 **19–120.1.**

28                                   **(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE**  
29 **MEANINGS INDICATED.**

30                                   **(2) “CERTIFICATE OF CONFORMANCE” MEANS AN APPROVAL**  
31 **ISSUED BY THE COMMISSION THAT ALLOWS AN ACUTE GENERAL HOSPITAL TO**

1 ESTABLISH PRIMARY PCI SERVICES OR NONPRIMARY PCI SERVICES WITHOUT  
2 A CERTIFICATE OF NEED.

3 (3) "CERTIFICATE OF ONGOING PERFORMANCE" MEANS AN  
4 APPROVAL ISSUED BY THE COMMISSION THAT THE CARDIAC SURGERY  
5 SERVICES, PRIMARY PCI SERVICES, OR NONPRIMARY PCI SERVICES PROVIDED  
6 BY AN ACUTE GENERAL HOSPITAL MEET STANDARDS EVIDENCING CONTINUED  
7 QUALITY.

8 (4) (I) "NONPRIMARY PCI" MEANS PCI CAPABLE OF  
9 RELIEVING CORONARY-VESSEL NARROWING ASSOCIATED WITH CORONARY  
10 ARTERY DISEASE UNRELATED TO ST-SEGMENT-ELEVATION MYOCARDIAL  
11 INFARCTION.

12 (II) "NONPRIMARY PCI" INCLUDES ELECTIVE PCI.

13 (5) "PCI" MEANS PERCUTANEOUS CORONARY INTERVENTION.

14 (6) (I) "PERCUTANEOUS CORONARY INTERVENTION" MEANS A  
15 PROCEDURE IN WHICH A CATHETER IS INSERTED INTO A BLOOD VESSEL AND  
16 GUIDED TO THE SITE OF THE NARROWING OF A CORONARY ARTERY TO RELIEVE  
17 CORONARY NARROWING.

18 (II) "PERCUTANEOUS CORONARY INTERVENTION"  
19 INCLUDES A VARIETY OF CATHETER-BASED TECHNIQUES, INCLUDING BALLOON  
20 ANGIOPLASTY.

21 (7) "PRIMARY PCI" MEANS PCI CAPABLE OF RELIEVING  
22 CORONARY VESSEL NARROWING ASSOCIATED WITH ST-SEGMENT-ELEVATION  
23 MYOCARDIAL INFARCTION.

24 (B) (1) BEGINNING JULY 1, 2012, BEFORE AN ACUTE GENERAL  
25 HOSPITAL MAY ESTABLISH PRIMARY PCI SERVICES OR NONPRIMARY PCI  
26 SERVICES, THE HOSPITAL SHALL OBTAIN A CERTIFICATE OF CONFORMANCE  
27 FROM THE COMMISSION.

28 (2) THE COMMISSION MAY NOT ISSUE A CERTIFICATE OF  
29 CONFORMANCE UNLESS THE COMMISSION FINDS THAT THE PROPOSED  
30 PRIMARY PCI SERVICES OR PROPOSED NONPRIMARY PCI SERVICES:

31 (I) ARE CONSISTENT WITH THE STATE HEALTH PLAN FOR  
32 FACILITIES AND SERVICES;

1                   **(II) WILL RESULT IN THE DELIVERY OF MORE EFFICIENT**  
2 **AND EFFECTIVE HEALTH CARE SERVICES; AND**

3                   **(III) ARE IN THE PUBLIC INTEREST.**

4           **(C) NOTWITHSTANDING SUBSECTION (B) OF THIS SECTION, A**  
5 **CERTIFICATE OF CONFORMANCE IS NOT REQUIRED FOR AN ACUTE GENERAL**  
6 **HOSPITAL TO ESTABLISH PRIMARY PCI SERVICES IF:**

7                   **(1) THE ACUTE GENERAL HOSPITAL WAS PROVIDING PRIMARY**  
8 **PCI SERVICES ON JANUARY 1, 2012; AND**

9                   **(2) THE COMMISSION DETERMINES THAT THE PRIMARY PCI**  
10 **SERVICES ARE CONSISTENT WITH THE STATE HEALTH PLAN FOR FACILITIES**  
11 **AND SERVICES.**

12           **(D) (1) THIS SUBSECTION APPLIES TO AN ACUTE CARE HOSPITAL**  
13 **THAT PROVIDES CARDIAC SURGERY OR PCI SERVICES UNDER:**

14                   **(I) A CERTIFICATE OF NEED ISSUED UNDER § 19-120 OF**  
15 **THIS SUBTITLE;**

16                   **(II) A CERTIFICATE OF CONFORMANCE ISSUED UNDER THIS**  
17 **SECTION; OR**

18                   **(III) AN EXCEPTION FROM THE CERTIFICATE OF**  
19 **CONFORMANCE REQUIREMENTS UNDER SUBSECTION (C) OF THIS SECTION.**

20                   **(2) AN ACUTE GENERAL HOSPITAL SHALL OBTAIN AND MAINTAIN**  
21 **A CERTIFICATE OF ONGOING PERFORMANCE TO CONTINUE TO PROVIDE:**

22                   **(I) CARDIAC SURGERY SERVICES;**

23                   **(II) PRIMARY PCI SERVICES; OR**

24                   **(III) NONPRIMARY PCI SERVICES.**

25           **(E) AN ACUTE GENERAL HOSPITAL THAT IS PROVIDING NONPRIMARY**  
26 **PCI SERVICES UNDER A RESEARCH WAIVER ISSUED BY THE COMMISSION**  
27 **SHALL OBTAIN A CERTIFICATE OF CONFORMANCE FOR ITS NONPRIMARY PCI**  
28 **SERVICES BEFORE THE ACUTE GENERAL HOSPITAL MAY OBTAIN A CERTIFICATE**  
29 **OF ONGOING PERFORMANCE TO PROVIDE THE NONPRIMARY PCI SERVICES.**

1           **(F) (1) THE COMMISSION SHALL ADOPT REGULATIONS THROUGH AN**  
2 **UPDATE TO THE STATE HEALTH PLAN FOR FACILITIES AND SERVICES TO**  
3 **IMPLEMENT THIS SECTION.**

4           **(2) THE REGULATIONS SHALL:**

5                   **(I) ADDRESS QUALITY, ACCESS, AND COST;**

6                   **(II) ESTABLISH A PROCESS AND MINIMUM STANDARDS FOR**  
7 **OBTAINING A CERTIFICATE OF CONFORMANCE;**

8                   **(III) ESTABLISH A PROCESS AND MINIMUM STANDARDS FOR**  
9 **OBTAINING AND MAINTAINING A CERTIFICATE OF ONGOING PERFORMANCE;**

10                   **(IV) SET AN APPROPRIATE TIME PERIOD FOR THE**  
11 **EXPIRATION OF A CERTIFICATE OF ONGOING PERFORMANCE; AND**

12                   **(V) REQUIRE, AS A CONDITION OF THE ISSUANCE OF A**  
13 **CERTIFICATE OF CONFORMANCE OR A CERTIFICATE OF ONGOING**  
14 **PERFORMANCE, THAT AN ACUTE GENERAL HOSPITAL AGREE TO VOLUNTARILY**  
15 **RELINQUISH ITS AUTHORITY TO PROVIDE CARDIAC SURGERY SERVICES,**  
16 **PRIMARY PCI SERVICES, OR NONPRIMARY PCI SERVICES IF THE HOSPITAL**  
17 **FAILS TO MEET THE APPLICABLE STANDARDS ESTABLISHED BY THE**  
18 **COMMISSION.**

19           SECTION 2. AND BE IT FURTHER ENACTED, That the process established  
20 by the Maryland Health Care Commission for issuing a certificate of conformance, as  
21 required under § 19–120.1 of the Health – General Article, as enacted by Section 1 of  
22 this Act:

23                   (1) shall be similar to the process through which the Commission  
24 grants an exemption from certificate of need requirements for merged asset systems;  
25 and

26                   (2) may not allow interested party status.

27           SECTION 3. AND BE IT FURTHER ENACTED, That, notwithstanding any  
28 other provision of this Act, an acute general hospital whose research waiver for  
29 nonprimary PCI services was extended by the Maryland Health Care Commission  
30 under COMAR 10.24.05 and that continues to meet the requirements under COMAR  
31 10.24.05 may provide nonprimary PCI services until the Commission:

32                   (1) makes one of the determinations or findings provided under  
33 COMAR 10.24.05.05; and

1                   (2) depending on the results of the C-PORT E study and the  
2 Commission's actions taken under COMAR 10.24.05.05A(1) and B, considers the  
3 hospital's application under § 19-120.1(b) of the Health – General Article, as enacted  
4 by Section 1 of this Act, for a certificate of conformance for its nonprimary PCI  
5 services.

6                   SECTION 4. AND BE IT FURTHER ENACTED, That this Act shall take effect  
7 July 1, 2012.